K031308

SEP 26 2003

RhiGene, Inc.
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SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS
MESACUP-2 Test Mitochondria M2
April 28, 2003

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The MESACUP-2 Test Mitochondria M2 is compared to a legally marketed predicate device and a substantial equivalence claim made. The predicate device is Quanta Lite Mitochondria M2 ELISA (K933180) currently manufactured and marketed by Inova Diagnostics, Inc, San Diego, California.

The MESACUP-2 Test Mitochondria M2 is an enzyme-linked immunosorbent assay (ELISA), utilizing the 96-microwell plate format, similar to the predicate device. Diluted serum samples, calibrator sera, and controls are incubated in microwells coated with mitochondria M2 antigens. Incubation allows the anti-mitochondria M2 antibodies present in the samples to react with the immobilized antigen. After the removal of unbound serum proteins by washing, antibodies specific for human immunoglobulins (IgG, IgM and IgA), labeled with horseradish peroxidase (HRP), are added forming complexes with the mitochondria M2 bound antibodies. Following another washing step, the bound enzyme-antibody conjugate is assayed by the addition of a single solution containing tetramethlybenzidine (TMB) and hydrogen peroxide (H_2O_2) as the chromogenic substrate. The intensity of the color generated is proportional to the serum concentration of anti-mitochondria M2 antibodies. Optical density is read spectrophotometrically at 450nm. The total incubation time (at room temperature) of the assay is 150 minutes. The assay makes use of two calibrators to measure the amount of anti-mitochondria M2 antibodies in patient samples.

The intended use of the device is a semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of anti-Mitochondrial antibodies in human serum as an aid in the diagnosis of primary biliary cirrhosis.

Performance indicates that MESACUP-2 Test Mitochondria M2 and the Quanta Lite Mitochondria M2 ELISA are equivalent. In-house studies indicate a clinical specificity of 100% for anti-mitochondria M2 antibodies in a healthy donor serum population for both the MESACUP-2 and Quanta Lite anti-mitochondria M2 methods. Additional comparison studies resulted a sensitivity of 91% and 95% respectively with a primary biliary cirrhosis population on the MESACUP-2 and Quanta Lite assays for anti-mitochondria M2 antibodies. Although differences between the assays are observed, in general, the performance characteristics are comparable. These results are also in compliance with those in published literature for anti-mitochondria M2 detection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 6 2003

RhiGene, Inc.
c/o Ms. Nanci Dexter
Director of Quality and Regulatory Affairs
Corgenix, Inc.
12061 Tejon Street
Westminster, Colorado 80234

Re: k031308
Trade/Device Name: Mesacup-2 Test Mitochondria M2
Regulation Number: 21 CFR § 866.5090
Regulation Name: Anti-Mitochondrial Antibody Immunological Test System
Regulatory Class: II
Product Code: DBM
Dated: August 28, 2003
Received: August 29, 2003

Dear Ms. Dexter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K031308

Device Name: Mesacup-2 Test Mitochondria M2

Indications for Use:

The MESACUP-2 TEST Mitochondria M2 is semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of anti-Mitochondrial antibodies in human serum as an aid in the diagnosis of primary biliary cirrhosis.

The MESACUP-2 TEST Mitochondria M2 is intended to be used by clinical (hospital and reference) laboratories.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FLOY 9/25/03

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031308

Prescription Use ✓